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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: June 24, 1999

MEMORANDUM

Subject: **PP8F5002.** Request for Permanent Tolerances for **Spinosad** on **Cucurbits (Crop Group 9), Legume Vegetables (Crop Group 6), Stone Fruit (Crop Group 12), Field Corn, Sweet Corn, Sorghum,** and **Wheat**. Evaluation of Analytical Chemistry and Residue Data.

DP Barcode:	D249374	Caswell No.:	None
Submission No.:	S548502	Prat Case No.:	290544
40 CFR:	180.495	Class:	Insecticide
PC Code:	110003	Trade Name:	SpinTor (62719-294), Success (62719-292), Tracer (62719-267)

MRID Nos.: 445977-01, -03, -04, -08 through -19

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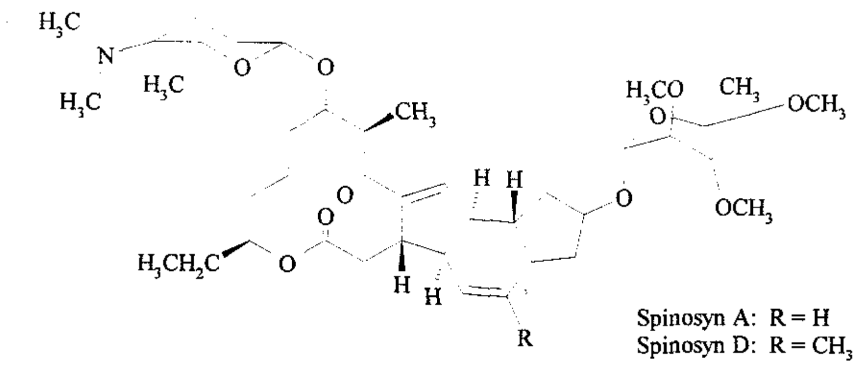
SPINOSAD



Spinosyn A: R = H
Spinosyn D: R = CH_3

SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- The registrant needs to submit a revised Section F. Tolerances need to be revised for the following commodities (HED-suggested values are in parenthesis):
  Aspirated grain fractions (20 ppm)
  Edible-podded legumes [Crop Subgroup 6A] (0.3 ppm)
  Succulent shelled peas and beans [Crop Subgroup 6B] (0.02 ppm)
  Dried shelled peas and beans [Crop Subgroup 6C] (0.02 ppm)
  Soybeans (0.3 ppm)
  Meat of cattle, goats, hogs, horses, and sheep (0.15 ppm)
  Meat byproducts of cattle, goats, hogs, horses, and sheep (1 ppm)
  Fat of cattle, goats, hogs, horses, and sheep (3.5 ppm)
  Milk, whole (0.5 ppm)
  Milk, fat (5 ppm)

- The registrant needs to submit a revised Section F with proposed tolerances for wheat processed commodities. HED recommends establishment of a time-limited tolerance of 0.15 ppm for residues of spinosad in wheat bran, flour, middlings, and shorts until the required wheat processing study is submitted and reviewed.

- In the interim, the registrant needs to submit a study depicting residues of spinosad in the processed wheat commodities of bran, flour, middlings, and shorts. Subsequent to receipt and review of that study, HED will reevaluate the appropriateness of the interim tolerances.

BACKGROUND

The petitioner, Dow AgroSciences, has submitted a petition for the registration and establishment of permanent tolerances for use of spinosad on cucurbit vegetables (Crop Group 9), stone fruits (Crop Group 12), legume vegetables (Crop Group 6), field corn, sweet corn, sorghum, and wheat. Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: **Spinosyn A** (Factor A; CAS# 131929-60-7) or 2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and **Spinosyn D** (Factor D; CAS# 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. The two active ingredients are typically present at an 85:15 (A:D) ratio.

Tolerances have been established in/on raw agricultural and animal commodities under 40 CFR §180.495 and are expressed in terms of residues of spinosad (spinosyns A and D). Tolerances range from 0.02 ppm (almonds) to 10 ppm (Brassica, leafy greens subgroup). HED has recently recommended for establishment of tolerances at 0.020 ppm for residues of spinosad in/on the tuberous and corn vegetables crop subgroup and, in conjuction with a Section 18 use for control of Mediterranean fruit fly, for tolerances of 0.02 ppm on all other foods.

Associated with this petition are data depicting the magnitude of spinosad residues in/on poultry meat and eggs (MRID 44597715), stone fruit (MRID 44597716), cucurbit vegetables (MRID 44597717), cereal grains (MRID 44597718), and legume vegetables (MRID 44597719). These data are presented and evaluated in this document.

CONCLUSIONS

OPPTS GLN 860.1200: Directions for Use

1. The proposed use directions for Success™ and SpinTor™ 2SC on cucurbits, legumes, and stone fruits are adequate, as are the use directions for Tracer™. The label for SpinTor™ 2SC needs to be modified for sweet corn to read "Do not apply within 1 day of harvest." and the labels for both Success™ and SpinTor™ 2SC should include restrictions against harvesting sweet corn forage within 7 days of the last application and sweet corn stover within 28 days of the last application. The registrant will need to submit a revised Section B.

OPPTS GLN 860.1300: Nature of the Residue - Plants and Animals

2. The qualitative nature of the residue in plants and animals is adequately understood. The parent compounds (spinosyns A and D) are the residues to be regulated in plant and animal commodities.

OPPTS GLN 860.1340: Residue Analytical Methods

3. Enforcement methods. Adequate methods are available for tolerance enforcement. The registrant proposes three immunoassay methods for tolerance enforcement for the subject-listed commodities and an HPCL/UV method for poultry commodities. All employ extraction regimes that have already been accepted by the Agency as a part of Agency-validated HPLC methods. Because of this and the fact that the Agency has found immunoassay method RES 95144 to be adequate for tolerance enforcement for spinosad-related residues in/on animal matrices, HED is not requiring petition method validation trials for these methods (GRM96.10.S1, GRM97.05, and GRM96.11.S1). These methods have undergone successful independent laboratory validation and will be forwarded to FDA for inclusion in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

4. In conjunction with PP#6G04692, the petitioner submitted data, which were forwarded to FDA (G. J. Herndon, 4/24/96), pertaining to the multiresidue methods testing of spinosyns A and D.

OPPTS GLN 860.1380: Storage Stability Data

5. Adequate storage stability data were submitted to support the field trials on cereal crops. Previously submitted studies have shown spinosad to be stable for at least six months in a number of commodities. Those studies are adequate to support the field trials on cucurbit and legume vegetables, stone fruit, and cereal grains and a feeding study on poultry.

OPPTS GLN 860.1500: Crop Field Trials

6a. The field trial data are adequate. Crop field trials support the establishment of tolerances at the requested levels for:

Cucurbit vegetables	0.30 ppm
Edible-podded legume vegetables (Subgroup 6A)	0.30 ppm
Stone fruits	0.20 ppm
Corn, grain, including field, sweet (K+CWHR), and pop	0.020 ppm
Wheat, grain	0.020 ppm
Sorghum, grain	1.0 ppm
Forage, fodder, hay, stover, and straw of cereal grains	1.0 ppm
Poultry, fat	0.20 ppm
Poultry, meat, meat byproducts, and eggs	0.020 ppm

6b. The registrant submitted data depicting residues of spinosad in sorghum aspirated grain fractions. This study shows residues of spinosad concentrate in aspirated grain fractions by a factor of 30X. As a result, HED calculated a toleranc for aspirated grain fraction of 20 ppm. The registrant will need to submit a revised Section F requesting an appropriate tolerance for aspirated grain fractions.

6c. The registrant has requested a tolerance at 0.30 ppm for the entire legume vegetable crop group. In order to grant a crop group tolerance, residues levels from field samples of representative crops must be within a 5-fold difference. This requirement is not met for legume vegetables (residue range is <0.016 to 0.23 ppm). For the studies conducted, only crop subgroup 6A, edible-podded legumes, is adequately represented. HED notes that IR-4 is planning to conduct field trials this year with crops in the 6B and 6C subgroups. Considering many of the similarities between soybeans and the crops in Subgroups 6B and 6C and the fact that all residues in soybeans were at or below the LOQ, HED recommends that time-limited tolerances be established at 0.02 ppm for both succulent shelled pea and bean (Subgroup 6B) and dried shelled pea and bean (Subgroup 6C). The registrant will need to submit a revised Section F requesting tolerances for edible-podded legumes (Subgroup 6A) at 0.3 ppm, succulent shelled pea and bean (Subgroup 6B) at 0.02 ppm, and dried shelled pea and bean (Subgroup 6C) at 0.02 ppm.

OPPTS GLN 860.1520: Processed Food/Feed

7a. *Cucurbit Vegetables*. There are no processed commodities associated with cucurbits. A discussion of processed commodities is not germane to this crop group.

7b. *Legume Vegetables*. Data from processing studies with legumes were not submitted with this petition. The legume vegetables crop group contains soybeans which have meal, hulls, and oil as processed commodities. From field trials conducted at a 5X application rate, residues in all but one soybean bean sample, which had residues at 0.02 ppm, were below the limit of quantitation (0.016 ppm). Given the nature of the spinosad molecule and the fact that the single finite residue is only slightly greater than the LOQ, HED will not require processing studies for soybeans.

7c. *Stone Fruits*. Data depicting residues in dried plums (i.e., prunes) were submitted with this petition. The only processed commodity from this crop group is prunes. These data indicate that resides of spinosad do not concentrate during the drying process. A separate tolerance is not required for prunes.

7d. *Cereal Crops*. Field studies with field corn and wheat harvested for grain were conducted at a 5X application rate. Since residues in field corn grain were below the LOD (0.005 ppm) for all samples, corn processing studies are not required. Finite residues were found in wheat grain treated at the 5X rate, with a highest average field trial of 0.09 ppm. In the absence of a wheat processing study, application of the highest theoretical concentration factors for wheat (8X) to the highest average field trial indicates that tolerances could be set for all wheat processed commodities at 0.15 ppm as an interim measure. The registrant must submit a processing study depicting residues of spinosad in wheat bran, flour, middlings, and shorts, and a revised Section F requesting tolerances at this level.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

8a. Milk, and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep. An acceptable cattle feeding study was reviewed in conjunction with a tolerance petition for apple and Brassica leafy vegetable commodities (PP#6F04761/6H05754; S. Willett, 1/23/97). As a result of the requested uses on cereal grains, the tolerances for spinosad in ruminant commodities will need to be increased. Based on HED calculations, the following tolerances are required:

Meat of cattle, goats, hogs, horses, and sheep	0.15	ppm
Meat byproducts of cattle, goats, hogs, horses, and sheep	1.0	ppm
Fat of cattle, goats, hogs, horses, and sheep	3.5	ppm

Milk, whole .... 0.40 ppm
Milk, fat .... 5.0 ppm

The registrant must submit a revised Section F reflecting these tolerance levels.

8b. Eggs, and the Fat, Meat, and Meat Byproducts of Poultry. The submitted poultry feeding study is adequate. Finite residues of spinosad may occur in poultry commodities. The study and field trial data support the requested tolerances listed under Conclusion 6, above.

OPPTS GLNs 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

9. No confined or field rotational crop studies were submitted with this petition. A rotational crop study with wheat, radish, and lettuce was submitted and reviewed in conjunction with PP#6G04692. The results of the confined rotational crop study indicate that the spinosad molecule was metabolized to the point where it entered the general carbon pool. It did not appear that the parent compound was taken up and/or translocated within the rotational crops tested. Extensive/limited rotational crop field studies need not be conducted and tolerances for rotational crops need not be established to support future permanent tolerance requests.

Other Considerations

10. No Codex, Canadian, or Mexican tolerances are established for spinosad. Harmonization is not an issue for this action.

RECOMMENDATIONS

Pending the results of the forthcoming human health risk assessment for PP8F5002 and the submission of revised Sections B and F, RAB2 recommends in favor of establishing **time-limited** tolerances at 0.02 ppm for spinosad in/on succulent shelled pea and bean (Subgroup 6B) and dried shelled pea and bean (Subgroup 6C) due to deficiencies noted in Conclusion 6C and in all processed wheat commodities (bran, flour, middlings, shorts) at 0.8 ppm due to the deficiency noted in Conclusion 7d. The petitioner must submit processing studies for wheat (Conclusion 7d), and a revised Section F for proposed tolerances on aspirated grain fractions (Conclusion 6b), legume vegetable crop subgroups (Conclusion 7b2), and on livestock commodities (Conclusion 8a). To summarize, tolerances for residues of spinosad should be established as follows:

Cucurbit vegetables (Crop Group 9) .... 0.30 ppm
Edible-podded legume vegetables (Crop Subgroup 6A) .... 0.30 ppm
Succulent shelled pea and bean (Crop Subgroup 6B) [Time-Limited] .... 0.02 ppm
Dried shelled pea and bean (Crop Subgroup 6C) [Time-Limited] .... 0.02 ppm
Soybean .... 0.02 ppm
Stone fruits (Crop group 12) .... 0.20 ppm
Corn, grain, including field, sweet (K+CWHR), and pop .... 0.020 ppm

Sorghum, grain	1.0	ppm
Wheat, grain	0.020	ppm
Wheat, flour, bran, middlings, and shorts [Time Limited]	0.15	ppm
Forage, fodder, hay, stover, and straw of cereal grains	1.0	ppm
Aspirated grain fractions	20	ppm
Meat of cattle, goats, hogs, horses, and sheep	0.15	ppm
Meat byproducts of cattle, goats, hogs, horses, and sheep	1.0	ppm
Fat of cattle, goats, hogs, horses, and sheep	3.5	ppm
Milk, whole	0.50	ppm
Milk, fat	5.0	ppm
Poultry, meat, meat byproducts, and eggs	0.020	ppm
Poultry, fat	0.20	ppm

DETAILED CONSIDERATIONS

OPPTS GLN 860.1200: Directions for Use

The petitioners provided specimen labels for SpinTor™ 2SC, Success™, and Tracer™. The proposed new uses for SpinTor™ and Success™ are on cucurbit crops, stone fruits, legume crops, and sweet corn. Both are 2 lb/gal aqueous suspension formulations. The proposed new uses for Tracer™ are on field corn, sorghum, soybeans, and wheat. Like SpinTor™ and Success™, Tracer™ is formulated as an aqueous suspension, but at 4 lb ai/gal. These formulations are to be broadcast applied (ground or air), but are not to be applied through an irrigation system (i.e., chemigation). The proposed use patterns for all three formulations are described below.

Use patterns for SpinTor™ and Success™ are identical, with the exception of application rates for sweet corn, and are summarized in Table 1. The proposed use patterns for Tracer™ are summarized in Table 2.

Conclusions: The proposed use directions for spinosad, as Success™, SpinTor™ 2SC, and Tracer™, on cucurbits, legumes, stone fruits, and cereal grain crops are adequate.

Table 1. Summary of Use Patterns for SpinTor™ and Success™.				
Use Parameters	Cucurbit Vegetables	Legume Vegetables	Stone Fruits	Sweet Corn
Application Rate, lb ai/A/Application	0.062 - 0.125	0.047 - 0.094	0.062 - 0.125	0.047 - 0.094 For SpinTor, 0.023 - 0.094
Application Timing	When pests appear	When pests appear	Determined by pest + location	Peak pest egg hatch
Maximum Number of Applications/Season	6	6	Not Specified	Not Specified
Application Interval, days	Determined by pest levels	Determined by pest levels; 3 days for European corn borer	Geographically determined	Determined by pest levels
Maximum Seasonal Rate, lb ai/A	0.45	0.45	0.45	0.45
Pre-harvest Interval, days	1(cucumbers) or 3 (others)	3	7 (cherries, plums, prunes) 14 (peaches, nectarines, apricots)	1

Table 2. Summary of Use Patterns for Tracer™.				
Use Parameters	Field Corn	Sorghum	Soybeans	Wheat
Application Rate, lb ai/A/Application	0.031 - 0.094	0.047 - 0.094	0.031 - 0.062	0.047 - 0.094
Application Timing	Peak pest egg hatch	Peak pest egg hatch	Determined by pest populations and onset of crop injury	Peak pest egg hatch
Maximum Number of Applications/Season	Not Specified	Not Specified	Not Specified	Not Specified
Application Interval, days	Determined by pest levels	Determined by pest levels; 3 - 5 for sorghum midge	Determined by pest levels	Determined by pest levels
Maximum Seasonal Rate, lb ai/A	0.188	0.45	0.186	0.28
Pre-harvest Interval, days	7 (forage) 28 (grain, fodder)	7 (grain, fodder) 14 (forage)	28	14 (forage, hay) 21 (grain, straw)
Other Restrictions	–	–	Do not feed treated forage or hay to meat or dairy animals	–

OPPTS GLN 860.1300: Nature of the Residue - Plants and Animals

The qualitative nature of the residue in plants and animals is adequately understood based on metabolism studies conducted with apples, cabbage, cotton, tomatoes, turnips, ruminants, and poultry. The HED Metabolism Committee has determined (2/3/98) that only the parent compounds (spinosyns A and D) are the residues to be regulated in plant and livestock commodities.

OPPTS GLN 860.1340: Residue Analytical Methods

Enforcement methods

Crops. The registrant has proposed the immunochemical methods GRM 96.10.S1(cereal grain commodities, cucurbits, and legumes), GRM 96.11.S1 (stone fruits), and GRM 97.05 (sorghum fodder) for tolerance enforcement. These methods all employ the extraction methods of the HPLC enforcement methods previously accepted by the Agency. The immunoassay methods typically require less sample cleanup than their HPLC counterparts; thus, transfer of extracted residues into the final extract should be equal to or greater than that which occurs with the HPLC methods. Briefly, residues of spinosad are extracted with acetonitrile + water (80 + 20, v/v), and cleaned up on a cyclohexyl (GRM 96.11.S1, 97.05) or C_{18} (GRM 96.10.S1) solid-phase extraction column. The extract is then evaporated to dryness, reconstituted in sample diluent, and analyzed by enzyme-linked immunosorbent assay. Sorghum fodder (GRM 97.05) requires partitioning of residues into methylene chloride prior to solid-phase extraction as an additional cleanup step. Both GRM 96.11.S1 and GRM 97.05 have undergone successful independent laboratory validation (MRID 44597708). A number of HPLC/UV and HPLC/MS methods are available for confirmation (e.g., GRM 96.09, GRM 97.06).

Livestock - Poultry. The registrant has submitted method GRM 95.15, "Determination of Spinosad and Metabolites in Poultry Tissues and Eggs by High Performance Liquid Chromatography with Ultraviolet Detection" (MRID 44597713). Residues of spinosad are extracted with 50% methanol + 50% acetonitrile (eggs), 60% hexane + 40% methylene chloride (fat), or 80% acetonitrile, 20% water (meat, liver, meat with overlying skin and associated fat). The extracts are then cleaned up with liquid-liquid partitioning followed by silica and cyclohexyl solid-phase extraction. Residues are then determined by HPLC with UV detection. This method is similar to other methods for analysis of spinosad in animal commodities.

Livestock - Ruminants. Method RES 95.14 (method for determination of spinosad residues in ruminant commodities using immunoassay) underwent successful independent lab validation and EPA lab validation, and has been submitted to FDA for inclusion in PAM II. Methods 95.03 (HPLC/UV) and 97.06 (HPLC/MS) are available as confirmatory methods.

Data depicting the suitability of these methods for data collection purposes are included in the Crop Field Trials section, below.

Conclusions: Adequate methods are available for tolerance enforcement. While the immunochemical methods GRM 96.10.S1, 96.11.S1, and 97.05 have not undergone Agency validation, the key components that make up the methods have been approved. Thus, petition method validations will not be required for these methods. The poultry method GRM 95.15 is similar to Agency-approved methods and does not require further validation. These methods will be forwarded to FDA for inclusion in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

The petitioner previously submitted data pertaining to multiresidue methods testing of spinosyns B and K and N-demethyl spinosyn D in conjunction with PP#6F4761/6H5754 which will be forwarded to FDA for review (S. Willett, 1/23/97). The petitioner had previously submitted data pertaining to the multiresidue methods testing of spinosyns A and D in conjunction with PP#6G04692 which were forwarded to FDA (G. J. Herndon, 4/24/96).

OPPTS GLN 860.1380: Storage Stability Data

Cucurbit Vegetables, Legume Vegetables, and Stone Fruit

Storage stability data were not submitted for the cucurbit, legume, or stone fruit commodities (except cherry) in this petition. From storage stability data previously submitted, spinosad has been shown to be stable during storage in a number of commodities: almonds (6 months), apples (6 months), cabbage (12 months), celery (7 months), cottonseed (9.5 months), spinach (7 months), and tomatoes (11 months). Those data are sufficient to support the crop field trial data submitted for the commodities in this review (maximum storage time = 130 days).

Cherries from the California field site were shipped refrigerated, rather than frozen. To determine the potential loss of spinosad during transit, a study was initiated to assess spinosad stability in/on cherries after two days under refrigerated conditions. Control cherry samples were fortified at 0.1 ppm. Recovery of spinosad on the day of treatment was 98%. After two days at 5°C, recovery was 92%; thus, there was no significant loss of spinosad residues from the cherry samples.

Cereal Crops

44597712. Frozen Storage Stability of Spinosad in field Corn Grain, Sweet Corn forage, and Sweet Corn Stover, Representative Crops of the Cereal Grains Group. 1998. Robb, C. K., Philips, A. M., and Young, D. L. Dow AgroSciences Study Number RES97043.

For the cereal crop commodities, storage stability data were submitted with this petition. Storage stability was assessed for spinosad in field corn grain, sweet corn forage, and sweet corn stover. Samples were fortified at 0.10 ppm with spinosad and analyzed using Method GRM 96.10, an immunochemical method with a validated limit of quantitation of 0.01 ppm. As shown in Table 3, spinosad did not decline under the storage conditions for any of the cereal grain commodities tested.

Table 3. Storage Stability of Spinosad in/on Cereal Grain Raw Agricultural Commodities

Storage Time, Days	Spinosad Remaining, % of Applied[1]		
	Grain	Forage	Stover
0	96	101	97
28	98	97	91
31	NS[2]	NS	93
97	87	98	92
191	89	91	93
342	93	98	98

[1] Fortification level equals 0.10 ppm spinosad
[2] NS = Not Sampled

Conclusions: In cereal grains, stover, and fodder, spinosad is stable under the storage conditions described for at least 342 days. No further storage stability data on cereal crop commodities are required to support this petition.

OPPTS GLN 860.1500: Crop Field Trials

Dow AgroSciences submitted four magnitude of residue studies, one each for cucurbit vegetables, legume vegetables, stone fruits, and cereal grains. Each study is discussed below.

Cucurbit Vegetables

44597717. Magnitude of Residue of Spinosad in Cucurbit Vegetables. 1998. Philips, A. M., Zabik, J. M., and Satonin, D. K. Dow AgroSciences Study Number RES97002.

As per a previous agreement with the Agency (Memo, S. Willett, 10/3/96), the registrant performed a reduced number of field trials to support the use of spinosad on cucurbit vegetables. Three, rather than five, trials were conducted for summer squash, with four treated samples being collected from each trial site. For the other representative cucurbit commodities (cucumbers and muskmelon), the full complement of six studies each were completed.

Field trials to support the use of spinosad on the cucurbit vegetable crop group were conducted on cucumber in Florida (Region 3), Michigan (Region 5), North Carolina (Region 2, 2 trials), Ohio (Region 5), and Texas (Region 6); muskmelon in California (Region 10, 3 trials), North Carolina, Ohio, and Texas; and on summer squash in California, Florida, and North Carolina. For all trials, six applications were made, with the first five being at approximately 0.066 lb ai/A and the sixth being at approximately 0.135 lb ai/A for total application rates ranging from 0.46 to 0.49 lb ai/A (1X the proposed maximum seasonal rate). At the Florida study site, a directed-spray application was used. All other sites were treated by broadcast spraying. Spray additives and/or adjuvants were not used. Pre-harvest intervals (PHIs) were 1 day following the final application to cucumbers and 3 days for muskmelon and summer squash. At harvest, a minimum of 12 fruit were manually collected from 12 randomly selected plants from each plot. For muskmelon, samples were composited by quartering the melons and combining the quarters from each of the 12 harvested melons. In addition to these samples, additional muskmelon quarters were taken from the California, Ohio, and Texas sites and the rind removed prior to compositing. These pulp-only samples are intended to provide residue estimates for dietary exposure analysis. Harvested samples were immediately placed on ice and were transported frozen to the Dow AgroSciences Environmental Chemistry Laboratory in Indianapolis, Indiana. The samples were stored frozen for up to 125 days prior to analysis. This time interval is supported by previous storage stability data. Samples were analyzed by the immunochemical Method GRM 96.10.S1, which has a limit of quantitation (LOQ) of 0.013 ppm and a limit of detection (LOD) of 0.005 ppm). This method is suitable for both tolerance enforcement and data collection; recovery of spinosad from fortified (0.01 - 0.25 ppm) control cucurbit samples analyzed concurrently with field trial samples averaged 93 ± 16%. Results of the field trial sample analyses are shown in Table 4. No apparent residues of spinosad were found in any control samples. Residues in the muskmelon samples with the rind removed were all less than 0.005 ppm. The registrant supplied adequate representative immunoassay data, including calibration curves. Residue decline data were not submitted with this petition.

Table 4. Summary of Spinosad Field Trials on Cucurbit Vegetables				
Crop	Study Location	Application Rate, lb ai/A	PHI, days	Residue, ppm
Cucumber	Hobe Sound, FL	0.472	1	0.05, 0.06
	Conklin, MI	0.465	1	0.07, 0.04
	Dallas, NC	0.472	1	<0.013, <0.013
	Shelby, NC	0.467	1	0.08, 0.06
	New Holland, OH	0.464	1	0.06, 0.05
	Brookshire, TX	0.466	1	0.02, 0.03
Muskmelon	Fresno, CA	0.472	3	0.12, 0.15
	Kettleman City, CA	0.469	3	0.02, 0.04
	El Centro, CA	0.461	3	0.03, 0.06
	Shelby, NC	0.479	3	0.07, 0.06
	New Holland, OH	0.460	3	0.22, 0.15
	Brookshire, TX	0.463	3	0.12, 0.09
Summer Squash	Fresno, CA	0.473	3	0.07, 0.03, 0.05, 0.04
	Hobe Sound, FL	0.476	3	0.03, 0.02, 0.02, 0.03
	Shelby, NC	0.488	3	<0.013, <0.013, <0.013, <0.013

Conclusions: The number, geographic distribution, storage conditions, and field trial results are all adequate to support a tolerance of 0.3 ppm for residues of spinosad in/on raw agricultural commodities in the cucurbit crop group (Crop Group 9), as requested by the petitioner. Considering the non-systemic nature of spinosad and its short half-life under field conditions, HED will assume that residues of spinosad will not increase with longer PHIs than those used in the field trials; thus, the lack of residue decline data is not considered a deficiency.

Legume Vegetables

44597719. Magnitude of Residues of Spinosad in Legumes. 1998. D. W. Roberts. Dow AgroSciences Study Number RES97034.

For the representative legume commodities, OPPTS Guideline 860.1500 calls for 12 trials with succulent beans, 9 trials with dried beans, 9 trials with succulent peas, 5 trials with dried peas, and 15 trials with soybeans. As per a previous agreement with the Agency (Memo, S. Willett, 10/3/96), the registrant performed a reduced number of field trials to support the use of spinosad on legume vegetables. Specifically, trials were conducted with snap beans (11 trials), snow peas (7 trials), and soybeans (7 trials at a 5X application rate). These trials were conducted in California, Florida, Indiana, Illinois, Iowa, Michigan, Missouri, Mississippi, New Jersey, North Carolina, Ohio, Oregon, Pennsylvania, Washington, and Wisconsin.

For all crops, applications were made as ground broadcast foliar sprays. For snap beans and snow peas, spinosad was applied in 6 treatments: 5 at 0.07 lb ai/A and 1 at 0.09 lb ai/A, for a total treatment rate of 0.44 lb ai/A (1X). Treatments were targeted at 3-day intervals, with the final treatment timed to occur 3 days before harvest. Soybeans received spinosad in 3 treatments, each at 0.34 lg ai/A, for a total treatment rate of 1.02 lb ai/A (5X). Applications were made on approximately 7-day intervals, with the final application timed to occur 28 days before harvest. Snap beans and snow pea pods were hand-picked from 12 randomly selected plants to give 3 lb of sample from each plot. Soybean seeds were harvested by mechanical combine (5 sites) or hand shear (NC and WI sites). Seeds were separated from the shell casing by the combine or by plastic bag and wooden dowel (NC) or by a threshing machine (WI). A composite sample, collected from 12 different areas and weighing approximately 3 lb, was obtained from each plot. All samples were placed directly into freezers at the field facility or were packed into coolers containing ice or dry ice for transport to freezer facilities within four hours of harvest. Samples were stored frozen during transport to the analytical laboratory (≤-10°C) and at the laboratory (≤-20°C) for up to 85 days prior to analysis. This time interval is supported by previous storage stability data. Legume crop group samples were analyzed by immunochemical method GRM 96.10.S1, which has a LOQ of 0.016 ppm and an LOD of 0.005 ppm. Additionally, residues of spinosad in North Carolina soybean samples were confirmed by Method GRM 96.09.R1 (HPLC/UV). Across all matrices, Method GRM 96.10.S1 gave recoveries of spinosad from fortified control samples of 107 ± 15%. Results of the field trial sample analyses are shown in Table 5. No apparent residues of spinosad were found in any control samples. The registrant supplied adequate immunoassay and HPLC data, including calibration curves and, in the case of HPLC, representative chromatograms. Analyses by HPLC agreed very well with those done by immunoassay. Residue decline data were not submitted with this petition.

Conclusions: The number, geographic distribution, storage conditions, and field trial results are all adequate to support a tolerances for residues of spinosad in/on raw agricultural commodities in the legume vegetable crop subgroups (Crop Group 6A, 6B, 6C). Considering the non-systemic nature of spinosad and its short half-life under field conditions, HED will assume that residues of spinosad will not increase with longer PHIs than those used in the field trials; thus, the lack of residue decline data is not considered a deficiency.

The registrant has requested a tolerance at 0.30 ppm for the entire legume vegetable crop group. In order to grant a crop group tolerance, residues levels from field samples of representative crops must be within a 5-fold difference. This requirement is not met for legume vegetables (residue range is <0.016 to 0.23 ppm). For the studies conducted, only crop subgroup 6A, edible-podded legumes, is adequately represented. HED notes that IR-4 is planning to conduct field trials this year with crops in the 6B and 6C subgroups. Considering many of the similarities between soybeans and the crops in Subgroups 6B and 6C and the fact that all residues in soybeans were at or below the LOQ, HED recommends that time-limited tolerances be established at 0.02 ppm for both succulent shelled pea and bean (Subgroup 6B) and dried shelled pea and bean (Subgroup 6C). The registrant will need to submit a revised Section F requesting tolerances for edible-podded legumes (Subgroup 6A) at 0.3 ppm, succulent shelled pea and bean (Subgroup 6B) at 0.02 ppm, and dried shelled pea and bean (Subgroup 6C) at 0.02 ppm

Table 5. Summary of Spinosad Field Trials on Legume Vegetables

Crop	Study Location	Application Rate, lb ai/A	PHI, days	Residue, ppm
Snap Bean	Fresno, CA	0.44	3	0.15, 0.14
	Fresno, CA	0.33	3	0.18, 0.16
	Oviedo, FL	0.42	3	0.02, 0.01
	Oviedo, FL	0.43	3	0.15, 0.13
	Noblesville, IN	0.41	3	0.02, 0.02
	Williamston, MI	0.44	3	0.03, 0.04
	Baptistown, NJ	0.39	3	0.09, 0.08
	Marysville, OH	0.44	3	0.06, 0.07
	Hamburg, PA	0.40	3	<0.016, <0.016
	Epharta, WA	0.44	3	0.01, 0.02
	Verona, WI	0.44	3	<0.016, <0.016
Snow Pea	Williamston, MI	0.45	3	0.23, 0.23
	Marysville, OH	0.40	3	0.22, 0.19
	Hillsboro, OR	0.40	3	0.07, 0.08
	Hamburg, PA	0.45	3	0.030, 0.031
	Ephrata, WA	0.38	3	0.039, 0.035
	Arkansaw, WI	0.40	3	<0.016, <0.016
	Verona, WI	0.44	3	<0.016, 0.016
Soybean	Jefferson, IA	1.00	28	<0.016, <0.016
	Carlyle, IL	1.01	28	<0.016, <0.016
	Greenfield, IN	1.00	28	<0.016, <0.016
	Columbia, MO	1.01	28	<0.016, <0.016
	Greenville, MS	1.03	28	<0.016, <0.016
	Greensboro, NC	1.03	28	0.02, <0.016
	Arkansaw, WI	1.02	28	<0.016, <0.016

Stone Fruits

44597716. Magnitude of Residue of Spinosad in Stone Fruit. 1998. Houtman, B. A., Philips, A. M., and Bolles, H. G. Dow AgroSciences Study Number RES97004.

For the representative stone fruit commodities, OPPTS Guideline 860.1500 calls for 7 trials with cherries (sweet or tart), 9 trials with peaches, and 6 trials with plums or fresh prunes. As per a previous agreement with the Agency (Memo, S. Willett, 10/3/96), the registrant performed a reduced number of field trials to support the use of spinosad on legume vegetables. Specifically, trials were conducted with plums (4 trials), prunes (2 trials), cherries (7 trials), and peaches (6 trials). These trials were conducted in California, Michigan, New York, North Carolina, Pennsylvania, South Carolina, Utah, Washington, and Wisconsin.

For each crop, applications were made at the dormant, bud, petal fall, and mature fruit (7 to 14 days prior to harvest) stages (4 applications total). For peaches, cherries, and plums, the total application rate ranged from 0.44 to 0.47 lb ai/A (1X); for prunes, the total rate was 1.56 lb ai/A (3.5X). Application was as a broadcast spray at 200 gal/A, though some cherry, peach, and plum trials were sprayed at 50 gal/A to determine the effects of spray volume on residues. All samples were manually harvested from a minimum of four trees per plot. Two to four samples were independently composited from each treated plot, with composited samples consisting of 2.5 to 5 lb of cherries or at least 24 fruits for plums, prunes, and peaches. Samples were stored frozen at the field facilities prior to shipment to the Dow AgroSciences Environmental Chemistry Laboratory (Indianapolis, IN). All samples were shipped frozen, with the exception of the cherries from the two California sites, which were shipped refrigerated (See Storage Stability Data for details). All samples were stored frozen (-20°C) at the analytical facility for up to 130 days prior to analysis. This time interval is supported by previous storage stability data. Samples were analyzed by Method GRM 96.11. This immunochemical method has a LOQ of 0.018 ppm and an LOD of 0.005 ppm for the samples in this study. Across all matrices, Method GRM 96.11 gave recoveries of spinosad from fortified and concurrently analyzed control samples of 89 ± 16%. Results of the field trial sample analyses are shown in Table 6. No apparent residues of spinosad were found in any control samples. The registrant supplied adequate immunoassay data to support the stone fruit crop field trials. Residue decline data were not submitted with this petition.

Conclusions: The number, geographic distribution, storage conditions, and field trial results are all adequate to support a tolerance of 0.2 ppm for residues of spinosad in/on raw agricultural commodities in the stone fruit crop group (Crop Group 12), as requested by the petitioner. Spray volume has no effect on residue levels. Considering the non-systemic nature of spinosad and its short half-life under field conditions, HED will assume that residues of spinosad will not increase with longer PHIs than those used in the field trials; thus, the lack of residue decline data is not considered a deficiency.

Table 6. Summary of Spinosad Field Trials on Stone Fruit Commodities				
Crop	Study Location	Application Rate, lb ai/A	PHI, days	Residue, ppm
Cherry	Patterson, CA	0.44 (200 gal/A)	7	0.07, 0.11
		0.46 (50 gal/A)	7	0.04, 0.03
	Mantaca, CA	0.45	7	0.06, 0.08
	Conklin, MI	0.45	7	0.03, 0.04
	Alton, NY	0.45	7	0.02, 0.02
	Perry, UT	0.45	7	0.10, 0.11
	Soap Lake, WA	0.45	7	0.14, 0.13
	Oregon, WI	0.44	7	<0.018, <0.018
Peach	Hanford, CA	0.45 (200 gal/A)	14	0.05, 0.06, 0.07, 0.07
		0.44 (50 gal/A)	14	0.06, 0.07, 0.05, 0.06
	Reedley, CA	0.47	14	0.06, 0.05, 0.04, 0.06
	Conklin, MI	0.45	14	<0.018, <0.018, <0.018, <0.018
	Lucama, NC	0.45	14	<0.005, <0.018, <0.018, <0.018
	Hereford, PA	0.45	14	<0.018, <0.018, <0.018, <0.018
	Batesburg, SC	0.45	14	0.03, 0.04, 0.02, 0.04
Plum	Hanford, CA	0.46 (200 gal/A)	7	<0.005, <0.005, <0.005, <0.005
		0.45 (50 gal/A)	7	<0.005, <0.005, <0.005, <0.005
	Reedley, CA	0.46	7	<0.005, <0.005, <0.005, <0.005
	Chico, CA	0.45	7	<0.018, <0.018, <0.018, <0.018
	Conklin, MI	0.45	7	<0.018, <0.018, <0.018, <0.018
Prune (fresh)	Visalia, CA	1.56	7	0.06, 0.07, 0.06, 0.08
	Merced, CA	1.57	7	0.07, 0.07, 0.05, 0.04
Prune (dried)	Visalia, CA	1.56	7	0.05, 0.08, 0.06, 0.07
	Merced, CA	1.57	7	0.03, 0.07, 0.05, 0.05

Cereal Grains

For the representative cereal grain commodities, OPPTS Guideline 860.1500 calls for 9 trials with sweet corn, 15 trials with field corn, 12 trials with rice, 9 trials with sorghum, and 15 trials with wheat. As per a previous agreement with the Agency (Memo, S. Willett, 10/3/96), the registrant performed a reduced number of field trials to support the use of spinosad on corn and wheat. Specifically, trials were conducted with sweet corn (9 trials), field corn (5 trials, each at

5X), and wheat (6 trials, each at 5X). This strategy was adopted due to the use patterns for spinosad and the nature of the commodities (i.e., the grain kernels are covered during treatment). For sorghum, whose kernels may be expose during spinosad application, a full complement (9) of field trials was conducted at the 1X rate. At this time, the petitioner does not seek tolerances for rice, hence no trials were conducted for this crop. The field trials were conducted in California, Colorado, Florida, Illinois, Indiana, Kansas, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Washington, and Wisconsin.

Sweet Corn. Spinosad was ground broadcast applied to sweet corn as five treatments, each at 0.09 lb ai/A on 3-day intervals, for a total application of 0.45 lb ai/A (1X). One day after the last spinosad treatment, a minimum of 12 ears of corn were collected from each field site. Forage and stover samples were composited from 12 plants. Forage was collected seven days after the last spinosad treatment; stover was collected 28 days after the last treatment. Storage details, analytical information and residue levels are summarized below.

Field Corn. Spinosad was ground broadcast applied to field corn as two treatments, each at 0.45 lb ai/A, at silking and at approximately 28 days before harvest. The total application was approximately 0.9 lb ai/A (5X). At harvest, approximately 5 lb of mature corn grain were composited from at least 12 areas of the plot. Storage details, analytical information and residue levels are summarized below.

Wheat. Spinosad was ground broadcast applied to wheat as three applications, each at either 0.09 lb ai/A (1X) or 0.45 lb ai/A (5X), at the early tillering, at boot stage, and at 21 days before harvest. The total application rate was either 0.27 lb ai/A or 1.35 lb ai/A. At each site, approximately 2.5 lb of mature wheat grain were harvested as a composite from at least 12 separate areas of the 5X-treated plot only. Forage, hay, and straw (four samples each) were collected from the 1X-treated plot only. Forage (2.5 lb) was composited from at least 12 areas of the plot 14 days after the first spinosad application. Hay was cut at 14 days after the second spinosad application and allowed to dry in the field prior to bagging. Straw (1.5 lb) was collected from at least 12 areas of the plot at the same time the grain was harvested. Grain and straw samples were harvested either manually or mechanically. Storage details, analytical information and residue levels are summarized below.

Sorghum. Spinosad was ground broadcast applied to sorghum as five applications, each at 0.09 lb ai/A, at 14 days after plant emergence, at head emergence, at soft dough stage, at hard dough stage, and at 7 days prior to grain harvest. The total application rate was 0.45 lb ai/A (1X). A minimum of 2.5 lb of mature sorghum grain was composited from at least 12 areas of the plot. Forage and stover samples were composited from 12 plants. Forage was collected 14 days after the third application and stover was collected 14 days after the final application. Residue decline data for grain, forage, and stover show residues of spinosad declining over a two- to three-week period. For grain, average residues were 0.85, 0.08, 0.09, and 0.04 ppm at days 0, 9, 14, and 21, respectively. For forage, average residues were 0.78, 1.2, 0.12, and 0.09

ppm on days 0, 3, 7, and 14, respectively. For stover, average residues were 1.60, 0.13, 0.08 and 0.19 ppm on days 0, 9, 14, and 21, respectively. Storage details, analytical information and residue levels are summarized below.

Samples from all field trials were placed into frozen storage within four hours of harvest and were shipped frozen to the Dow AgroSciences Environmental Chemistry Laboratory (Indianapolis , IN) for analysis. At the analytical facility, samples were stored at -20 °C for a maximum of 214 days prior to analysis. This interval is supported by the submitted storage stability data which showed residues to be stable for at least 342 days (see above). Samples were analyzed by Method GRM 96.10.S1 (except sorghum fodder, which used GRM 97.05). These immunochemical methods have limits of detection and quantitation, and concurrent recoveries as shown in Table 7. Across all matrices, recoveries of spinosad from fortified and concurrently analyzed control samples were 98 ± 13%. Results of the field trial sample analyses are shown in Table 9. No apparent residues of spinosad were found in any control samples. The registrant supplied adequate immunoassay data to support the cereal grain crop field trials. Residue decline data from sorghum grain at the Mississippi field trial indicates that spinosad is fairly stable until around 14 days, at which time it decreases rapidly. Spinosad decreased rapidly in sorghum forage after 7 days. In stover, residues declined rapidly between Day 0 and Day 9, but then remained fairly consisitent.

Table 7. Limits of Detection and Quantitation, and Spinosad Recoveries for Cereal Crop Analytical Methods

Sample Matrix	Method	LOD, ppm	LOQ, ppm	Recovery, % Mean	Recovery, % Std. Dev.
Sweet and Field Corn Grain	GRM 96.10.S1	0.005	0.012	99	14
Sweet Corn Forage and Stover	GRM 96.10.S1	0.006	0.021	97	17
Sorghum Grain and Aspirated Grain Fractions	GRM 97.05	0.005	0.013	102	13
Sorghum Forage and Stover	GRM 97.05	0.005	0.024	92	13
Wheat Grain	GRM 96.10.S1	0.007	0.013	102	10
Wheat Forage, Hay, and Straw	GRM 96.10.S1	0.005	0.016	93	14

Table 8. Spinosad Residue Decline in Sorghum Commodities

Grain		Forage		Stover	
PHI, days	Average Residue, ppm	PHI, days	Average Residue, ppm	PHI, days	Average Residue, ppm
0	0.85	0	0.78	0	1.60
9	0.08	3	1.20	9	0.13
14	0.09	7	0.12	14	0.08
21	0.04	14	0.09	21	0.19

Table 9. Summary of Spinosad Field Trials on Cereal Grain Commodities				
Crop	Study Location	Application Rate, lb ai/A[1]	PHI, days	Residue, ppm
Sweet Corn, Ears (Kernel + Cob w/ Husk Removed	Fresno, CA	0.45	1	<0.005, <0.005
	Oviedo, FL	0.45	1	<0.005, <0.005
	Carleton, MI	0.46	1	<0.005, <0.005
	Theilman, MN	0.46	1	<0.005, <0.005
	Dallas, NC	0.46	1	<0.005, <0.005
	North Rose, NY	0.46	1	<0.005, <0.005
	Hillsboro, OR	0.46	1	<0.005, <0.005
	Eureka, WA	0.46	1	<0.005, <0.005
	Arkansaw, WI	0.46	1	<0.005, <0.005
Sweet Corn, Forage	Fresno, CA	0.45	7	0.49, 0.64
	Oviedo, FL	0.45	7	0.19, 0.18
	Wyoming, IL	0.45	7	0.06, 0.12
	Carleton, MI	0.46	7	0.20, 0.10
	Theilman, MN	0.46	7	0.41, 0.49
	Dallas, NC	0.46	7	0.21, 0.17
	North Rose, NY	0.46	7	0.09, 0.09
	New Holland, OH	0.48	7	0.33, 0.39
	Hillsboro, OR	0.46	7	0.10, 0.10
	Hamburg, PA	0.46	7	0.07, 0.10
	Eureka, WA	0.46	7	0.17, 0.21
	Arkansaw, WI	0.46	7	0.47, 0.57
Sweet Corn, Stover	Fresno, CA	0.45	28	0.84, 0.80
	Oviedo, FL	0.45	28	0.10, 0.07
	Wyoming, IL	0.45	28	0.13, 0.07
	Carleton, MI	0.46	28	<0.005, 0.02
	Theilman, MN	0.46	28	0.15, 0.19
	Dallas, NC	0.46	28	0.16, 0.12
	North Rose, NY	0.46	28	0.19, 0.12
	New Holland, OH	0.48	28	0.24, 0.23
	Hillsboro, OR	0.46	28	0.06, 0.04
	Hamburg, PA	0.46	28	0.11, 0.11

Crop	Study Location	Application Rate, lb ai/A[1]	PHI, days	Residue, ppm
	Eureka, WA	0.46	28	0.47, 0.64
	Arkansaw, WI	0.46	28	0.13, 0.11
Field Corn, Grain	Theilman, MN	0.94	27	<0.005, <0.005
	Dallas, NC	0.91	30	<0.005, <0.005
	York, NE	0.91	30	<0.005, <0.005
	New Holland, OH	0.89	28	<0.005, <0.005
	Shoemakersville, PA	0.92	28	<0.005, <0.005
Sorghum, Grain	Eaton, CO	0.44	7	0.78, 0.58
	Robinson, KS	0.45	7	0.08, 0.09
	Oregon, MO	0.44	7	0.02, 0.04
	Greenville, MS	0.45	9	0.08, 0.08
	York, NE	0.44	7	0.34, 0.65
	Grand Island, NE	0.45	8	0.15, 0.20
	Colony, OK	0.44	7	0.17, 0.20
	East Bernard, TX	0.45	7	0.16, 0.16
	Claude, TX	0.45	7	0.13, 0.11
Sorghum, Forage	Robinson, KS	0.27	14	0.08, 0.09
	Greenville, MS	0.27	14	<0.005, 0.09
	York, NE	0.27	14	0.08, 0.12
	Colony, OK	0.26	14	0.05, 0.06
	East Bernard, TX	0.27	14	0.16, 0.21
Sorghum, Stover	Robinson, KS	0.45	15	00.06, 0.07
	Greenville, MS	0.45	14	0.09, 0.06
	York, NE	0.45	14	0.14, 0.10
	Colony, OK	0.44	14	0.24, 0.34
	East Bernard, TX	0.45	14	0.15, 0.07
Wheat, Grain	Geneseo, IL	1.37	21	0.02, <0.013
	Greenfield, IN	1.36	21	<0.005, <0.005
	Velva, ND	1.32	21	0.06, 0.05
	Goodwell, OK	1.33	21	0.05, 0.08
	Barnard, SD	1.34	21	0.07, 0.05
	Groom, TX	1.33	21	0.10, 0.08

Crop	Study Location	Application Rate, lb ai/A[1]	PHI, days	Residue, ppm
Wheat, Forage	Geneseo, IL	0.09	14	0.07, 0.06, 0.09, 0.06
	Greenfield, IN	0.09	14	<0.016, <0.016, <0.016, <0.016
	Velva, ND	0.09	14	<0.005, <0.005, <0.005, <0.005
	Goodwell, OK	0.09	14	<0.016, 0.018, 0.016, 0.018
	Barnard, SD	0.09	14	<0.016, <0.016, <0.016, <0.016
	Groom, TX	0.09	14	0.08, 0.06
			15	0.05, 0.05
Wheat, Hay	Geneseo, IL	0.18	14	0.07, 0.05, 0.06, 0.06
	Greenfield, IN	0.18	14	<0.016, <0.016, <0.016, <0.005
	Velva, ND	0.17	14	0.02, 0.02, 0.02, 0.02
	Goodwell, OK	0.18	14	0.06, 0.06, 0.05, 0.06
	Barnard, SD	0.18	14	0.12, 0.13, 0.17, 0.12
	Groom, TX	0.18	14	0.19, 0.25, 0.22, 0.15
Wheat, Straw	Geneseo, IL	0.27	21	0.22, 0.24, 0.19, 0.26
	Greenfield, IN	0.27	22	<0.016, <0.016, <0.016, <0.016
	Velva, ND	0.26	21	0.53, 0.98, 0.63, 0.78
	Goodwell, OK	0.27	21	0.77, 0.54, 0.61, 0.57
	Barnard, SD	0.27	21	0.82, 0.45, 0.52, 0.46
	Groom, TX	0.27	21	0.42, 0.54, 0.39, 0.41

[1] Total spinosad applied prior to harvest.

The registrant submitted, as part of the crop field trials, data depicting residues of spinosad in sorghum aspirated grain fractions. From the field trials in Mississippi, bulk samples of treated (0.07 ppm spinosad) and control sorghum grain were collected and shipped to the Food Protein Research and Development Center (Bryan, TX) for processing into aspirated grain fractions. The processing method used simulates industrial practices used in terminal elevators to remove grain dust. Processed fractions were shipped frozen to Dow AgroSciences (Indianapolis, IN) for analysis. Residues were analyzed by Method GRM 97.05 and were found at levels of 1.9, 1.9, and 2.1 ppm. The average residue of 2.0 ppm gives a concentration factor of approximately 30X. The highest average field trial (HAFT) from the cereal grains comes from sorghum and is 0.68 ppm from the trial in Eaton, CO. Applying the concentration factor of 30X to this residue level gives a value of approximately 20 ppm. The registrant is required to submit a revised Section F specifying a tolerance of 20 ppm for aspirated grain fractions.

Conclusions: The number, geographic distribution, storage conditions, and field trial results are all adequate to support the requested tolerances on cereal grain raw agricultural commodities:

Corn, grain (including field, sweet, and pop)	0.02	ppm
Wheat, grain	0.02	ppm
Sorghum, grain	1.0	ppm
Forage, fodder, hay, and straw of corn, sorghum, and wheat	1.0	ppm

The registrant will need to submit a revised Section F specifying a tolerance of 20 ppm for aspirated grain fractions.

OPPTS GLN 860.1520: Processed Food/Feed

Cucurbit Vegetables

As there are no regulated processed commodities from the cucurbit crop group, a discussion of residues in cucurbit vegetable processed food/feed is not germane to this petition.

Legume Vegetables

For the legume vegetable crop group, only soybeans have processed commodities. These include meal, hulls, and refined oil. Of 14 residue values for soybean seed from the field trials run at a 5X rate, only one had finite residue and that value was only slightly greater than the LOD. Because of these results and the nature of the spinosad molecule, HED does not require a processing study for soybean.

Conclusions: Processing studies are not required for soybean meal, halls, or refined oil. Residues in these commodities are not expected to exceed the tolerance for soybean seed (0.02 ppm).

Stone Fruits

The only processed commodity for the stone fruit crop group is prunes. The petitioner submitted data depicting residues of spinosad in prunes dried from samples of fresh prunes harvested from the two prune field trials (treated at 3.5X). A description of the drying process was not provided. Because of the exaggerated treatment rate and the facts that there was not concentration of residues and that residues in both the RAC and the dried fruit were well below the proposed tolerance, HED will assume that the drying process followed typical industrial processes and will not require further processing details. From the first trial, the average residue of spinosad in fresh prunes was 0.068 ppm while the residue from the dried samples averaged 0.065 ppm. Similarly in the second trial, spinosad residues averaged 0.058 ppm in fresh prunes and 0.050 ppm in dried prunes (See Table 6 for individual values).

Conclusions: Residues of spinosad do not concentrate upon drying of fresh prunes. A separate tolerance is not required for dried prunes.

Cereal Grains

Data regarding processed cereal crop commodities were not provided. The cereal grains have the following processed commodities: corn meal, corn oil, wheat bran, wheat flour, wheat middlings, and wheat shorts. From the field corn trials, residues in field corn treated at a 5X rate were all < LOD; thus, a processing study is not needed for corn. However, wheat grain samples treated at a 5X rate had a HAFT of 0.09 ppm. The maximum theoretical processing factors for wheat processed commodities is 8X. Applying the 8X factor to one fifth of the HAFT gives a calculated residue of 0.14 ppm. This value is greater than the proposed tolerance of 0.020 ppm for wheat grain: therefore, processing studies are required for wheat processed commodities. As an interim measure, HED will support a time-limited tolerance of 0.15 ppm on wheat bran, flour, middlings, and shorts. These tolerances will be reevaluated upon receipt and review of a wheat processing study.

Conclusions: HED will support a time-limited tolerance of 0.15 ppm on wheat processed commodities. The registrant needs to submit processing studies for wheat bran, flour, middlings, and shorts and a revised Section F requesting tolerances for these commodities at 0.15 ppm. Upon receipt and review of the processing study, HED will reevaluate the appropriateness of the time-limited tolerances

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

The inclusion of cereal grains in the registered uses of spinosad may cause an increase in the maximum theoretical dietary burden experienced by livestock (Table 10). Note that these values are greater than those determined by the registrant because of their incorrect computation for the aspirated grain fraction tolerance.

Table 10. Calculation of Maximum Theoretical Dietary Burden

				% of Diet				Dietary Burden, ppm			
Crop	Commodity	Residue, ppm	% DM[3]	Beef	Dairy	Swine	Poultry	Beef	Dairy	Swine	Poultry
Sorghum	AGF[4]	20	85	20	20	20	—	4.7	4.7	4.7	0.0
Corn	Forage	1	40	40	50	—	—	1.0	1.3	0.0	0.0
Sorghum	Grain	1	86	40	30	80	80	0.5	0.3	0.9	0.9
Wheat	Grain	0.02	89	—	—	—	20	0.0	0.0	0.0	0.0
			∑	100	100	100	100	6.2	6.3	5.6	0.9

[1] % DM = Percent Dry Matter
[2] Dietary Burden = Residue ÷ % DM × % of Diet
[3] Dietary Burden = Residue × % of Diet/100
[4] AGF = Aspirated Grain Fractions

Ruminants

An acceptable cattle feeding study was reviewed in conjunction with a tolerance petition for apple and Brassica leafy vegetable commodities (PP#6F04761/6H05754; S. Willett, 1/23/97). Linear interpolation between the 3- and 10-ppm feeding levels from that study gives the transfer coefficients and calculated residues shown in Table 11.

Table 11. Summary of Spinosad Cattle Feeding Study and Determination of Transfer Coefficients

Commodity	Dosing Level, ppm			Transfer Coefficient[a]	Calculated Residue, ppm[b]
	1	3	10		
	Average Residue after 28 Days, ppm[c]				
Muscle	0.018	0.041	0.178	0.019	0.12
Fat	0.544	1.047	4.753	0.529	3.33
Kidney	0.047	0.163	0.445	0.040	0.25
Liver	0.095	0.273	0.981	0.101	0.64
Milk, whole	0.049	0.157	0.559	0.057	0.36
Cream	0.197	0.634	2.157	0.217	1.37
Milk, skim	0.008	0.019	0.095	0.011	0.07

[a] Linear interpolation between the 3- and 10-ppm dosing levels = $(\text{Residue}_{10} - \text{Residue}_3)/(10-3)$
[b] Transfer coefficient × dietary burden (6.3 ppm).
[c] Average of summed spinosyns A+D

Using the registrant's estimate of a concentration factor of 12.5 for spinosad in milk fat, the calculated residue for that commodity is 4.6 ppm. Note that for cream, the transfer coefficient is 0.217, giving a calculated residue of 1.4 ppm. Given that cream is approximately 20 to 40% fat, the registrants concentration factor for milk fat is reasonable and indicates that a tolerance of 5 ppm is appropriate for milk fat. With the exception of kidney, these values are in excess of the proposed tolerances for these commodities. For skim milk, the calculated transfer coefficient is 0.011. This results in a calculated residue of 0.07 ppm. This value should be used in the dietary analysis for milk-based water.

Poultry

44597715. Magnitude of Residues of Spinosad in Meat and Eggs for a Poultry Feeding Study. 1998. Gardner, R. C. and Dolder, S. C. Dow Agro Sciences Study Number RES95050.

The registrant conducted a poultry feeding study in which five groups of laying hens (9 birds/group) were dosed for 42 days via gelatin capsule at 0, 0.1, 0.3, 1, or 5 ppm spinosad. Eggs were collected daily and composited in groups of three for analysis. Tissue collected on Day 42 from the hens was composited similarly. Analysis was by HPLC method GRM 95.15 or GRM 95.15.R1 for all matrices. The LOQ and LOD was 0.01 and 0.003 ppm, respectively, for eggs, muscle, and liver; and 0.03 and 0.01 ppm, respectively, for fat. Results from concurrently run fortified control samples show the methods to be acceptable (89 ± 12% for eggs, 105 ± 15% for fat, and 99 ± 9% for tissues). Storage stability studies show spinosad to be stable in eggs for up to 638 days, in fat for up to 608 days, in muscle for up to 568 days, and in liver for up to 584 days. For the magnitude of residue study, egg samples were stored for up to 551 days: other matrices were stored for up to 372 days.

Residues in eggs reached a maximum on Day 13, with an average residue of 0.24 ppm. Residues at later time periods (Days 28, 35, and 41) ranged from 0.14 to 0.19 ppm at the 5-ppm rate. No residues were observed in eggs or tissues from any of the control animals.

Table 12. Summary of Spinosad Residues in Poultry Commodities

Matrix[1]	Dosing Level, ppm			
	0.1	0.3	1.0	5.0
	Average Residue, ppm			
Eggs	<0.003	<0.003	<0.003	0.242
Muscle	<0.003	<0.003	<0.003	0.066
Fat	<0.03	0.04	0.14	1.23
Liver	<0.003	<0.003	0.01	0.09

[1] For egg, after 13 days of dosing. For others, after 41 days of dosing.

Based on the calculated dietary burden of 0.9 ppm, residues in poultry commodities at the 1-ppm feeding level are adequate to set tolerances. The tolerances proposed by the registrant are in agreement with both the dietary burden estimates and the residues observed in the poultry feeding study (i.e., tolerances of 0.20 ppm for fat and 0.020 ppm for meat, meat byproducts, and eggs).

Conclusions: The magnitude of residue study for poultry is adequate as are the proposed poultry tolerances. The tolerances for ruminant commodities proposed by the registrant are not supported by the submitted data. The registrant is required to submit a revised Section F requesting tolerances for cattle, goats, hogs, horses, and sheep at 0.15 ppm for meat, 1.0 ppm for meat byproducts, and 3.5 ppm for fat. For milk, tolerances should be 0.5 ppm in whole milk and 5.0 ppm in milk fat.

OPPTS GLNs 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

No confined or field rotational crop studies were submitted with this petition. A rotational crop study with wheat, radish, and lettuce was submitted and reviewed in conjunction with PP#6G04692. The results of the confined rotational crop study indicate that the spinosad molecule was metabolized to the point where it entered the general carbon pool. It did not appear that the parent compound was taken up and/or translocated within the rotational crops tested. Extensive/limited rotational crop field studies need not be conducted and tolerances for rotational crops need not be established to support a future permanent tolerance request.

Other Considerations

No Codex, Canadian, or Mexican tolerances are established for spinosad. Harmonization is not an issue for this action.

cc: M. Doherty, RAB2 Reading File

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Chemical:	**Spinosad (proposed common name for Facto**
PC Code:	**110003**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	***06/24/99***
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